



(11) EP 0 724 894 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
07.08.1996 Bulletin 1996/32

(51) Int. Cl.⁶: A61N 5/06

(21) Application number: 96300756.2

(22) Date of filing: 02.02.1996

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL
PT SE

(30) Priority: 03.02.1995 US 383509

(71) Applicant: ESC Medical Systems Ltd.
31905 Haifa (IL)

(72) Inventor: Eckhouse, Shimon
Haifa, 34987 (IL)

(74) Representative: Cardwell, Stuart Martin et al
Roystons
Tower Building
Water Street
Liverpool, Merseyside L3 1BA (GB)

(54) Method and apparatus for therapeutic electromagnetic treatment

(57) A therapeutic treatment device for treating a treatment region comprising an incoherent, pulsed, light source operable to provide a light output for treatment, a power supply connected to the light source, a housing including a reflector and having an opening, wherein the light source is disposed within the housing and the reflector reflects light from the light source to the opening. A flexible light guide is disposed between the opening and the treatment region, wherein the light guide receives the incoherent light from the light source and transmits the light to the treatment region and the light source, reflector and light guide cooperate to provide between 6 and 100 J/cm² to the skin.

The light guide transmits light having a predetermined angular divergence, wherein the divergence is selected in response to a desired treatment depth.

EP 0 724 894 A2

Description

The present invention relates generally to the art of therapeutic electromagnetic treatment and more specifically to a method and apparatus for utilizing a spatially extended pulsed light source such as a flashlamp (flash tube) for such a treatment or, efficiently focusing light from the flashlamp into optical fibers for therapeutic treatment or other applications.

This application is a continuation-in-part of prior co-pending United States application Serial No. 07/964,210, filed October 20, 1992, entitled "Method And Apparatus For Therapeutic Electromagnetic Treatment."

It is known in the prior art to use electromagnetic radiation in medical application for therapeutic uses such as treatment of skin disorders. For example, U.S. Patent No. 4,298,005 to Mutzhas describes a continuous ultraviolet lamp with cosmetic, photobiological, and photochemical applications. A treatment based on using the UV portion of the spectrum and its photochemical interaction with the skin is described. The power delivered to the skin using Mutzhas' lamp is described as $150\text{W}/\text{m}^2$, which does not have a significant effect on skin temperature.

In addition to prior art treatment involving UV light, lasers have been used for dermatological procedures, including Argon lasers, CO_2 lasers, Nd(Yag) lasers, Copper vapor lasers, ruby lasers and dye lasers. For example, U.S. Patent No. 4,829,262 to Furumoto, describes a method of constructing a dye laser used in dermatology applications. Two skin conditions which may be treated by laser radiation are external skin irregularities such as local differences in the pigmentation or structure of the skin, and vascular disorders lying deeper under the skin which cause a variety of skin abnormalities including port wine stains, telangiectasias, leg veins and cherry and spider angiomas. Laser treatment of these skin disorders generally includes localized heating of the treatment area by absorption of laser radiation. Heating the skin changes or corrects the skin disorder and causes the full or partial disappearance of the skin abnormality.

Certain external disorders such as pigmented lesions can also be treated by heating the skin very fast to a high enough temperature to evaporate parts of the skin. Deeper-lying vascular disorders are more typically treated by heating the blood to a high enough temperature to cause it to coagulate. The disorder will then eventually disappear. To control the treatment depth a pulsed radiation source is often used. The depth the heat penetrates in the blood vessel is controlled by controlling the pulse width of the radiation source. The absorption and scattering coefficients of the skin also affect the heat penetration. These coefficients are a function of the constituents of skin and the wavelength of the radiation. Specifically, the absorption coefficient of light in the epidermis and dermis tends to be a slowly varying, monotonically decreasing function of wavelength. Thus, the wavelength of the light should be chosen so that the absorption coefficient is optimized for the particular skin condition and vessel size being treated.

The effectiveness of lasers for applications such as tattoo removal and removal of birth and age marks is diminished because lasers are monochromatic. A laser of a given wavelength may be effectively used to treat a first type of skin pigmentation disorder, but, if the specific wavelength of the laser is not absorbed efficiently by skin having a second type of disorder, it will be ineffective for the second type of skin disorder. Also, lasers are usually complicated, expensive to manufacture, large for the amount of power delivered, unreliable and difficult to maintain.

The wavelength of the light also affects vascular disorder treatment because blood content in the vicinity of the vascular disorders varies, and blood content affects the absorption coefficient of the treatment area. Oxyhemoglobin is the main chromophore which controls the optical properties of blood and has strong absorption bands in the visible region. More particularly, the strongest absorption peak of oxyhemoglobin occurs at 418nm and has a band-width of 60nm. Two additional absorption peaks with lower absorption coefficients occur at 542 and 577nm. The total band-width of these two peaks is on the order of 100nm. Additionally, light in the wavelength range of 500 to 600nm is desirable for the treatment of blood vessel disorders of the skin since it is absorbed by the blood and penetrates through the skin. Longer wavelengths up to 1000nm are also effective since they can penetrate deeper into the skin, heat the surrounding tissue and, if the pulse-width is long enough, contribute to heating the blood vessel by thermal conductivity. Also, longer wavelengths are effective for treatment of larger diameter vessels because the lower absorption coefficient is compensated for by the longer path of light in the vessel.

Accordingly, a wide band electromagnetic radiation source that covers the near UV and the visible portion of the spectrum would be desirable for treatment of external skin and vascular disorders. The overall range of wavelengths of the light source should be sufficient to optimize treatment for any of a number of applications. Such a therapeutic electromagnetic radiation device should also be capable of providing an optimal wavelength range within the overall range for the specific disorder being treated. The intensity of the light should be sufficient to cause the required thermal effect by raising the temperature of the treatment area to the required temperature. Also, the pulse-width should be variable over a wide enough range so as to achieve the optimal penetration depth for each application. Therefore, it is desirable to provide a light source having a wide range of wavelengths, which can be selected according to the required skin treatment, with a controlled pulse-width and a high enough energy density for application to the affected area.

Pulsed non-laser type light sources such as linear flashtlamps provide these benefits. The intensity of the emitted light can be made high enough to achieve the required thermal effects. The pulse-width can be varied over a wide range so that control of thermal depth penetration can be accomplished. The typical spectrum covers the visible and ultraviolet range and the optical bands most effective for specific applications can be selected, or enhanced using fluorescent

materials. Moreover, non-laser type light sources such as flashlamps are much simpler and easier to manufacture than lasers, are significantly less expensive for the same output power and have the potential of being more efficient and more reliable. They have a wide spectral range that can be optimized for a variety of specific skin treatment applications. These sources also have a pulse length that can be varied over a wide range which is critical for the different types of skin treatments.

In addition to being used for treating skin disorders, lasers have been used for invasive medical procedures such as lithotripsy and removal of blood vessel blockage. In such invasive procedures laser light is coupled to optical fibers and delivered through the fiber to the treatment area. In lithotripsy the fiber delivers light from a pulsed laser to a kidney or gallstone and the light interaction with the stone creates a shock wave which pulverizes the stone. To remove blood vessel blockage the light is coupled to the blockage by the fiber and disintegrates the blockage. In either case the shortcomings of lasers discussed above with respect to laser skin treatment are present. Accordingly, a treatment device for lithotripsy and blockage removal utilizing a flashlamp would be desirable.

To effectively treat an area the light from the source must be focussed on the treatment area. Coupling pulsed laser light into optical fibers in medicine is quite common. The prior art describes coupling isotropic incoherent point sources such as CW lamps into small optical fibers. For example, U. S. Patent No. 4,757,431, issued July 12, 1988, to Cross, et al. discloses a method for focusing incoherent point sources with small filaments or an arc lamp with an electrode separation of 2mm into a small area. Point (or small) sources are relatively easy to focus without large losses in energy because of the small size of the source. Also, U. S. Patent No. 4,022,534, issued May 10, 1977, to Kishner discloses light produced by a flash tube and the collection of only a small portion of the light emitted by the tube into an optical fiber.

However, the large dimension of an extended source such as a flashlamp makes it difficult to focus large fractions of its energy into small areas. Coupling into optical fibers is even more difficult since not only must a high energy density be achieved, but the angular distribution of the light has to be such that trapping in the optical fiber can be accomplished. Thus, it is desirable to have a system for coupling the output of a high intensity, extended, pulsed light source into an optical fiber.

According to a first embodiment of the invention a therapeutic treatment device comprises a housing and an incoherent light source, suitably a flashlamp, operable to provide a pulsed light output for treatment, disposed in the housing. The housing has an opening and is suitable for being disposed adjacent a skin treatment area. A reflector is mounted within the housing proximate the light source, and at least one optical filter is mounted proximate the opening in the housing. An iris is mounted coextensively with the opening. Power to the lamp is provided by a variable pulse width pulse forming circuit. Thus, the treatment device provides controlled density, filtered, pulsed light output through an opening in the housing to a skin area for treatment.

According to a second embodiment of the invention a method of treatment with light energy comprises the steps of providing a high power, pulsed light output from a non-laser, incoherent light source and directing the pulsed light output to a treatment area. The pulse width of the light output is controlled and focussed so that the power density of the light is controlled. Also, the light is filtered to control the spectrum of the light.

According to a third embodiment of the invention a coupler comprises an incoherent light source such as a toroidal flashlamp. A reflector is disposed around the incoherent light source and at least one optical fiber or light guide. The fiber has an end disposed within the reflector. This end collects the light from the circular lamp. In a similar coupling configuration fibers may be provided, along with a linear to circular fiber transfer unit disposed to receive light from the light source and provide light to the optical fibers. The reflector has an elliptical cross-section in a plane parallel to the axis of the linear flash tube, and the linear flash tube is located at one focus of the ellipse while the linear to circular transfer unit is located at the other focus of the ellipse.

For a better understanding of the invention, reference is made to the accompanying drawings, in which like numerals designate corresponding elements or sections throughout, and in which:

Figure 1 is a cross-sectional view of an incoherent, pulsed light source skin treatment device;

Figure 2 is a side view of the light source of Figure 1;

Figure 3 is a schematic diagram of a pulse forming network with a variable pulse width for use with the skin treatment device of Figures 1 and 2;

Figure 4 is a cross-sectional view of a coupler for coupling light from a toroidal flash tube into an optical fiber with a conical edge;

Figure 5 is a side view of a toroidal flash tube;

Figure 6 is a top view of a toroidal flash tube;

Figure 7 shows the geometry for coupling into a conical section;

Figure 8 is a cross-sectional view of a coupler for coupling light from a toroidal flash tube into an optical fiber with a flat edge;

Figure 9 is a front sectional view of a coupler for coupling light from a linear flash tube into a circular fiber bundle;

Figure 10 is a side sectional view of the coupler of Figure 9;

Figure 11 is a front view of a coupler for coupling light from a linear flash tube into an optical fiber;
 Figure 12 is a front view of a coupler for coupling light from a linear flash tube into a doped optical fiber;
 Figure 13 is a schematic configuration of a gel skin interface with a transparent plate;
 Figure 14 shows an angular distribution of photons penetrating without using a gel;
 Figure 15 shows a light guide providing a large angular divergence;
 Figure 16 shows a light guide providing a narrow angular divergence;
 Figure 17 shows a spectra produced with a flashlamp current of 200 amps;
 Figure 18 shows a spectra produced with a flashlamp current of 200 amps; and
 Figure 19 shows a GTO driver circuit for a flashlamp.

In the various figures, like reference numerals are used to describe like components.

Before explaining at least one embodiment of the invention in detail it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Referring now to Figures 1 and 2, cross-sectional and side views of an incoherent, pulsed light source skin treatment device 10 constructed and operated in accordance with the principles of the present invention are shown. The device 10 may be seen to include a housing 12, having an opening therein, a handle 13 (Figure 2 only), a light source 14 having an outer glass tube 15, an elliptical reflector 16, a set of optical filters 18, an iris 20 and a detector 22 (Figure 1 only).

Light source 14, which is mounted in housing 12, may be a typical incoherent light source such as a gas filled linear flashlamp Model No. L5568 available from ILC. The spectrum of light emitted by gas filled linear flashlamp 14 depends on current density, type of glass envelope material and gas mixture used in the tube. For large current densities (e.g., 3000 A/Cm² or more) the spectrum is similar to a black body radiation spectrum. Typically, most of the energy is emitted in the 300 to 1000nm wavelength range.

To treat a skin (or visible) disorder a required light density on the skin must be delivered. This light density can be achieved with the focusing arrangement shown in Figures 1 and 2. Figure 1 shows a cross-section view of reflector 16, also mounted in housing 12. As shown in Figure 1, the cross-section of reflector 16 in a plane is perpendicular to the axis of flashlamp 14 is an ellipse. Linear flashlamp 14 is located at one focus of the ellipse and reflector 16 is positioned in such a way that the treatment area of skin 21 is located at the other focus. The arrangement shown is similar to focusing arrangements used with lasers and efficiently couples light from flashlamp 14 to the skin. This arrangement should not, however, be considered limiting. Elliptical reflector 16 may be a metallic reflector, typically polished aluminum which is an easily machinable reflector and has a very high reflectivity in the visible, and the UV range of the spectrum can be used. Other bare or coated metals can also be used for this purpose.

Optical and neutral density filters 18 are mounted in housing 12 near the treatment area and may be moved into the beam or out of the beam to control the spectrum and intensity of the light. Typically, 50 to 100nm bandwidth filters, as well as low cutoff filters in the visible and ultraviolet portions of the spectrum, are used. In some procedures it is desirable to use most of the spectrum, with only the UV portion being cut off. In other applications, mainly for deeper penetration, it is preferable to use narrower bandwidths. The bandwidth filters and the cutoff filters are readily available commercially.

Glass tube 15 is located coaxially with flashlamp 14 and has fluorescent material deposited on it. Glass tube 15 will typically be used for treatment of coagulation of blood vessels to optimize the energy efficiency of device 10. The fluorescent material can be chosen to absorb the UV portion of the spectrum of flashlamp 14 and generate light in the 500 to 650nm range that is optimized for absorption in the blood. Similar materials are coated on the inner walls of commercial fluorescent lamps. A typical material used to generate "warm" white light in fluorescent lamps has a conversion efficiency of 80%, has a peak emission wavelength of 570nm and has a bandwidth of 70nm and is useful for absorption in blood. The few millisecond decay time of these phosphors is consistent with long pulses that are required for the treatment of blood vessels.

Other shapes or configurations of flashlamp 14 such as circular, helical, short arc and multiple linear flashlamps may be used. Reflector 16 may have other designs such as parabolic or circular reflectors. The light source can also be used without a reflector and the required energy and power density may be achieved by locating light source 14 in close proximity to the treatment area.

Iris 20 is mounted in housing 12 between optical filters 18 and the treatment area and controls the length and the width of the exposed area, i.e. by collimating the output of flashlamp 14. The length of flashlamp 14 controls the maximum length that can be exposed. Typically an 8cm long (arc length) tube will be used and only the central 5cm of the tube is exposed. Using the central 5cm assures a high degree of uniformity of energy density in the exposed skin area. Thus, in this embodiment the iris 20 (also called a collimator) will enable exposure of skin areas of a maximum length of 5cm. The iris 20 may be closed to provide a minimum exposure length of one millimeter. Similarly, the width of the

exposed skin area can be controlled in the range of 1 to 5mm for a 5mm wide flashlamp. Larger exposed areas can be easily achieved by using longer flash tubes or multiple tubes, and smaller exposure areas are obtainable with an iris that more completely collimates the beam. The present invention provides a larger exposure area compared to prior art lasers or point sources and is very effective in the coagulation of blood vessels since blood flow interruption over a longer section of the vessel is more effective in coagulating it. The larger area exposed simultaneously also reduces the required procedure time.

Detector 22 (Figure 1) is mounted outside housing 12 and monitors the light reflected from the skin. Detector 22 combined with optical filters 18 and neutral density filters can be used to achieve a quick estimate of the spectral reflection and absorption coefficients of the skin. This may be carried out at a low energy density level prior to the application of the main treatment pulse. Measurement of the optical properties of the skin prior to the application of the main pulse is useful to determine optimal treatment conditions. As stated above, the wide spectrum of the light emitted from the non-laser type source enables investigation of the skin over a wide spectral range and choice of optimal treatment wavelengths.

In an alternative embodiment, detector 22 or a second detector system may be used for real-time temperature measurement of the skin during its exposure to the pulsed light source. This is useful for skin thermolysis applications with long pulses in which light is absorbed in the epidermis and dermis. When the external portion of the epidermis reaches too high a temperature, permanent scarring of the skin may result. Thus, the temperature of the skin should be measured. This can be realized using infra-red emission of the heated skin, to prevent over-exposure.

A typical real-time detector system would measure the infra-red emission of the skin at two specific wavelengths by using two detectors and filters. The ratio between the signals of the two detectors can be used to estimate the instantaneous skin temperature. The operation of the pulsed light source can be stopped if a preselected skin temperature is reached. This measurement is relatively easy since the temperature threshold for pulsed heating that may cause skin scarring is on the order of 50°C or more, which is easily measurable using infra-red emission.

The depth of heat penetration depends on the light absorption and scattering in the different layers of the skin and the thermal properties of the skin. Another important parameter is pulse-width. For a pulsed light source, the energy of which is absorbed in an infinitesimally thin layer, the depth of heat penetration (d) by thermal conductivity during the pulse can be written as shown in Equation 1:

$$d = 4 [k\Delta t/C\rho]^{1/2} \quad (\text{Eq. 1})$$

where

k = heat conductivity of the material being illuminated;
 Δt = the pulse-width of the light pulse;
 C = the heat capacity of the material;
 ρ = density of the material.

It is clear from Equation 1 that the depth of heat penetration can be controlled by the pulse-width of the light source. Thus, a variation of pulse-width in the range of 10^{-5} sec to 10^{-1} sec will result in a variation in the thermal penetration by a factor of 100.

Accordingly, the flashlamp 14 provides a pulse width of from 10^{-5} sec to 10^{-1} sec. For treatment of vascular disorders in which coagulation of blood vessels in the skin is the objective the pulse length is chosen to uniformly heat as much of the entire thickness of the vessel as possible to achieve efficient coagulation. Typical blood vessels that need to be treated in the skin have thicknesses in the range of 0.5mm. Thus, the optimal pulse-width, taking into account the thermal properties of blood, is on the order of 100msec. If shorter pulses are used, heat will still be conducted through the blood to cause coagulation, however, the instantaneous temperature of part of the blood in the vessel and surrounding tissue will be higher than the temperature required for coagulation and may cause unwanted damage.

For treatment of external skin disorders in which evaporation of the skin is the objective, a very short pulse-width is used to provide for very shallow thermal penetration of the skin. For example, a 10^{-5} sec pulse will penetrate (by thermal conductivity) a depth of the order of only 5 microns into the skin. Thus, only a thin layer of skin is heated, and a very high, instantaneous temperature is obtained so that the external mark on the skin is evaporated.

Figure 3 shows a variable pulse-width pulse forming circuit comprised of a plurality of individual pulse forming networks (PFN's) that create the variation in pulse-widths of flashlamp 14. The light pulse full width at half maximum (FWHM) of a flashlamp driven by a single element PFN with capacitance C and inductance L is approximately equal to:

$$\Delta t = 2[LC]^{1/2} \quad (\text{Eq. 2})$$

Flashlamp 14 may be driven by three different PFN's, as shown in Figure 3. The relay contacts R1', R2' and R3' are used to select among three capacitors C1, C2 and C3 that are charged by the high voltage power supply. Relays R1,

R2 and R3 are used to select the PFN that will be connected to flashlamp 14. The high voltage switches S1, S2 and S3 are used to discharge the energy stored in the capacitor of the PFN into flashlamp 14. In one embodiment L1, L2 and L3 have values of 100mH, 1mH and 5mH, respectively, and C1, C2 and C3 have values of 100mF, 1mF and 10mF, respectively.

In addition to the possibility of firing each PFN separately, which generates the basic variability in pulse-width, additional variation can be achieved by firing PFN's sequentially. If, for example, two PFN's having pulse-width Δt_1 and Δt_2 are fired, so that the second PFN is fired after the first pulse has decayed to half of its amplitude, then an effective light pulse-width of this operation of the system will be given by the relation: $\Delta t = \Delta t_1 + \Delta t_2$.

The charging power supply typically has a voltage range of 500V to 5kV. The relays should therefore be high voltage relays that can isolate these voltages reliably. The switches S are capable of carrying the current of flashlamp 14 and to isolate the reverse high voltage generated if the PFN's are sequentially fired. Solid-state switches, vacuum switches or gas switches can be used for this purpose.

A simmer power supply (not shown in Figure 3) may be used to keep the flashlamp in a low current conducting mode. Other configurations can be used to achieve pulse-width variation, such as the use of a single PFN and a crow-bar switch, or use of a switch with closing and opening capabilities.

Typically, for operation of flashlamp 14 with an electrical pulse-width of 1 to 10msec, a linear electrical energy density input of 100 to 300J/cm can be used. An energy density of 30 to 100J/cm² can be achieved on the skin for a typical flashlamp bore diameter of 5mm. The use of a 500 to 650nm bandwidth transmits 20% of the incident energy. Thus, energy densities on the skin of 6 to 20J/cm² are achieved. The incorporation of the fluorescent material will further extend the output radiation in the desired range, enabling the same exposure of the skin with a lower energy input into flashlamp 14.

Pulsed laser skin treatment shows that energy densities in the range of 0.5 to 10J/cm² with pulse-widths in the range of 0.5msec are generally effective for treating vascular related skin disorders. This range of parameters falls in the range of operation of pulsed non-laser type light sources such as the linear flashlamp. A few steps of neutral density glass filters 18 can also be used to control the energy density on the skin.

For external disorders a typical pulse-width of 5 microsecond is used. A 20J/cm electrical energy density input into a 5mm bore flashlamp results in an energy density on the skin of 10J/cm². Cutting off the hard UV portion of the spectrum results in 90% energy transmission, or skin exposure to an energy density of close to 10 J/cm². This energy density is high enough to evaporate external marks on the skin.

Device 10 can be provided as two units: a lightweight unit held by a physician using handle 13, with the hand-held unit containing flashlamp 14, filters 18 and iris 20 that together control the spectrum and the size of the exposed area and the detectors that measure the reflectivity and the instantaneous skin temperature. The power supply, the PFN's and the electrical controls are contained in a separate box (not shown) that is connected to the hand-held unit via a flexible cable. This enables ease of operation and easy access to the areas of the skin that need to be treated.

The invention has thus far been described in conjunction with skin treatment. However, using a flashlamp rather than a laser in invasive treatments provides advantages as well. Procedures such as lithotripsy or removal of blood vessel blockage may be performed with a flashlamp. Such a device may be similar to that shown in Figures 1 and 2, and may use the electronics of Figure 3 to produce the flash. However, to properly couple the light to an optical fiber a number of couplers 40, 80 and 90 are shown in Figures 4 and 8-10, respectively.

Coupler 40 includes an optical source of high intensity incoherent and isotropic pulsed light such as a linear flash tube 42, a light reflector 44 which delivers the light energy to an optical fiber 46. The latter has a generally conical edge in the embodiment of Figure 4. Optical fiber 46 transfers the light from light collection system 44 to the treatment area. In general, coupler 40 couples pulsed light from a flash tube into an optical fiber and has applications in medical, industrial and domestic areas.

For example, coupler 40 may be used in material processing to rapidly heat or ablate a portion of a material being processed, or to induce a photo-chemical process. Alternatively, coupler 40 may be used in a photography application to provide a flash for picture taking. Using such a coupler would allow the flash bulb to be located inside the camera, with the light transmitted to outside the camera using an optical fiber. As one skilled in the art should recognize coupler 40 allows the use of incoherent light in many applications that coherent or incoherent light has been used in the past.

To provide for coupling the light to an optical fiber, flash tube 42 has a toroidal shape, shown in Figures 5 and 6, and is disposed inside reflector 44. In addition to the toroidal shape other shapes, such as a continuous helix, may be used for flash tube 42. However, a helical tube is more difficult to manufacture than a toroidal tube. Referring now to Figure 6, flash tube 42 is generally in the shape of a torus, but is not a perfect torus since the electrodes located at the end of the torus have to be connected to the power source. This does not create a significant disturbance in the circular shape of flash tube 42, since the connection to the electrodes can be made quite small.

Reflector 44 collects and concentrates the light, and has a cross-section of substantially an ellipse, in a plane perpendicular to the minor axis of the toroidal flash tube 42. The major axis of this ellipse preferably forms a small angle with the major axis of toroidal lamp 42. The exact value of the angle between the ellipse axis and the main axis of lamp 42 depends on the Numerical Aperture (NA) of the optical fiber. The toroidal flash tube is positioned so that its minor

axis coincides with the focus of the ellipse. The other focus of the ellipse is at the edge of optical fiber 46. Reflector 44 may be machined from metal with the inner surfaces polished for good reflectivity. Aluminum is a very good reflector with high reflectivity in the visible and ultraviolet wavelengths, and it may be used for this purpose. The reflector can be machined in one piece and then cut along a surface perpendicular to the main axis of the device. This will enable integration of the toroidal flash tube into the device.

As shown in Figure 4, the edge of optical fiber 46 is a cone with a small opening angle, so that the total area of the fiber exposed to the light from the flash tube is increased. Referring now to Figure 7 the geometry for coupling light into a conical tip is shown. It is assumed here that the light comes from a region in space with a refractive index of n_2 and that the conical section of the fiber (as well as the rest of the fiber core) has a refractive index of n_1 .

Not all the light rays hitting the cone are trapped in it. For light rays that propagate in a plane that contains the major axis of the system, a condition can be derived for the angle of a ray that will be trapped and absorbed in the fiber. This condition is shown in Equation 3.

$$\sin(\mu_{crit}) = \cos(\beta) \cdot [n_1^2/n_2^2 - 1]^{1/2} \sin(\beta) \quad (\text{Eq. 3})$$

Light will be trapped in the conical portion of the optical fiber if the incidence angle μ is larger than μ_{crit} calculated from Equation 3. Trapping is possible only if $n_1 > n_2$. If the medium outside of the fiber is air, $n_2 = 1$. Not all of the light trapped in the conical section of the fiber will also be trapped in the straight portion of the fiber if a fiber with a core and a cladding is used. If a fiber with a core and no cladding is used (air cladding), then all the rays captured in the conical section of the fiber will also be trapped in the straight section of the fiber.

The configuration shown in Figure 4 can also be used with a fluid filling the volume between the reflector and the optical fiber. A very convenient fluid for this purpose may be water. Water is also very effective in cooling the flashlamp if high repetition rate pulses are used. The presence of a fluid reduces the losses that are associated with glass to air transitions, such as the transition between the flashlamp envelope material and air. If a fluid is used in the reflector volume, then its refractive index can be chosen such that all the rays trapped in the conical section are also trapped in the fiber, even if core/cladding fibers are used.

Another way of configuring the fiber in the reflector is by using a fiber with a flat edge. This configuration is shown in Figure 8 and has trapping efficiency very close to the trapping efficiency of the conical edge. Many other shapes of the fiber edge, such as spherical shapes, can also be used. The configuration of the fiber edge also has an effect on the distribution of the light on the exit side of the fiber and it can be chosen in accordance with the specific application of the device.

The device may be used with a variety of optical fibers. Single, or a small number of millimeter or sub-millimeter diameter fibers, will typically be used in invasive medical applications. In other applications, particularly in industrial and domestic applications, it may be preferable to use a fiber having a larger diameter, or a larger bundle of fibers, or a light guide.

According to one embodiment flexible or rigid light guides are used to couple the light to the treatment area. Flexible light guides made from a bundle of quartz or other glass fibers that are fused together by heat at the edge of the bundles. The bundles may be circular, rectangular, or any other useful shape. Rigid light guides may be made from quartz, acrylic, glass, or other materials having a high degree of transparency. The material is generally highly polished on all sides.

A typical cross section of a circular light guide useful for therapeutic treatment is one mm to ten mm in diameter. Alternatively, a rectangular light guide may be used having typical dimensions of 3 mm by 10 mm to 30 mm by 100 mm. In either case the length may be 20 to 300 mm, or as needed for the specific application.

According to another alternative embodiment a rectangular light guide is used to more efficiently couple the light. The rectangular light guide is chosen to have a shape that matches a rectangular linear flashlamp and to match the shape of the vessel being treated.

The light guides described above may be used in another alternative embodiment to control the spectrum of light delivered to the treatment area. Spectral control can be achieved by making the light guide from a material that had an absorbing dye dissolved therein. Thus, light transmitted by the light guide will have a spectrum in as determined by the absorbing dye. Alternatively, a flat, discrete filter may be added to one end (preferably the input end) of the light guide. Both of these filters are absorbing filters. The inventors have found that absorbing filters produced by Schott, having Model Nos. OG515, OG550, OG570, and OG590 have suitable characteristics.

Additionally, interference filters or reflective coatings on the light guide may be used by applying a proper optical coating to the light guide. Again, a single discrete interference filter could also be used. Additionally, combinations of the various filters described herein, or other filters, may be used. The use of the filters described here may render the use of the filters described earlier with reference to Figure 1 redundant.

An alternative embodiment entails the use of application specific light guides. In this way the spectra of light for various treatments can be easily controlled. According to this alternative each type of treatment will be performed with a specific light guide.

The optical properties of the light guide will be chosen to optimize the particular treatment. The wavelengths below are particularly useful for the respective treatments:
 arteries less than 0.1 mm in diameter - 520-650nm
 veins less than 0.1 mm in diameter - 520-700nm
 vessels between 0.1 and 1.0 mm in diameter - 550-1000nm
 larger vessels - 600-1000nm
 In each case if the skin is darker (higher pigmentation) longer wavelengths on the lower cut-off portion of the spectrum should be used.

Multiple spectra may be used for optimal penetration. This may be accomplished by illuminating with a few pulses, each having a different spectrum. For example, the first pulse can have a spectrum that is highly absorbed in blood. This pulse will coagulate the blood, thereby changing the optical properties of the blood, making it more absorbing in another wavelength range (preferably longer). A second pulse will be more efficiently absorbed since the blood absorbs energy of a greater wavelength range. This principle may be used with lasers or other light sources as well.

In addition to the features of the light guides discussed above, a light guide is used, in one alternative embodiment, to control the angular distribution of the light rays impinging on the skin. Light that impinges on the skin at large angles (relative to the perpendicular) will not penetrate very deeply into the tissue. Conversely, light that impinges perpendicularly to the skin will have a deeper penetration. Thus, it is desirable to provide a distribution of light rays that has a relatively wide angular divergence when the treatment requires shallow penetration. Alternatively, a narrow divergence is preferable for treatment requiring deep penetration is desired. Some treatment might require both shallow and deep penetration.

Figure 15 shows a light guide 115 having an exit beam with a greater angular divergence than that of the entrance beam. As shown in Figure 15, a beam 116 enters light guide 115 at a small angle, relative to the axis of light guide 115. When beam 501 exits light guide 115, the angle, relative to the axis, is much greater. The tapered shape of light guide 115 enhances this divergence.

Figure 16 shows a straight light guide 118 that maintains the angular distribution of the rays of light that enter into it. A beam 119 is shown entering and exiting light guide 118 with the same angle, relative to the axis of coupler 601. Alternate use of both light guides 115 and 118 can achieve the narrow and deep penetration discussed above. Alternatively, the user can select the type of coupler according to the depth of penetration needed for the treatment being performed.

Figures 9 and 10 show a coupler 90 for coupling a linear flash tube 92 through a linear to circular fiber transfer unit 94 to a fiber bundle 96. A reflector 98 has an elliptical cross-section, shown in Figure 10, in a plane parallel to the axis of linear flash tube 92 in this embodiment. Tube 92 is located on one focus of the ellipse while the linear side of linear to circular bundle converter 94 is located at the other focus of the ellipse. This configuration is relatively simple to manufacture and commercially available linear to circular converters such as 25-004-4 available from General Fiber Optics may be used. This configuration is particularly useful for larger exposure areas of the fiber, or for flash illumination purposes.

The energy and power densities that can be achieved by this invention are high enough to get the desired effects in surface treatment or medical applications. For the embodiment shown in Figure 4 the total energy and power densities can be estimated as follows. For a typical toroidal lamp with a 4mm bore diameter and a major diameter of 3.3cm an electrical linear energy density input of 10J/cm into the lamp can be used with a 5μsec pulse width. The light output of the lamp will be 5 to 6J/cm for optimal electrical operating conditions. For the reflector shown in Figure 4, 50% of the light generated in the lamp will reach the lower focus. Thus, a total energy flux on the focus of 25 to 30J may be obtained. For embodiments shown in Figure 4 or Figure 8 the total cross-section area of reflector at the focal plane has a cross-section of 0.8cm². Energy densities on the order of 30 to 40J/cm² at the entrance to the fiber should be attained with this cross-section. This corresponds to power densities of 5 to 10MW/cm², which are the typical power densities used in medical or material processing applications.

For longer pulses, higher linear electrical energy densities into the lamp can be used. For a 1msec pulse to the flash tube a linear electrical energy density of 100J/cm can be used. The corresponding energy density at the focal area would be up to 300J/cm². Such energy densities are very effective in industrial cleaning and processing applications as well as in medical applications.

Alternative embodiments for coupling the optical fiber to an extended light source such as a linear flashlamp are shown in Figures 11 and 12. In the embodiment of Figure 11 an optical fiber 101 is wound around a lamp 102 and a lamp envelope 103. Some of the light that is produced by the light source is coupled into the fiber. If the light rays are propagating in the direction that is trapped by the fiber then this light will propagate in the fiber and it can be used at a fiber output 104. One limitation of this configuration is the fact that most of the light emitted by lamp 103 travels in a direction perpendicular to the surface of lamp 103 and cannot be trapped in fiber 101.

The embodiment shown in Figure 12 overcomes this problem. A doped optical fiber 105 is wound around lamp 102 and envelope 103, rather than an undoped fiber such as fiber 101 of Figure 11. The dopant is a fluorescent material which is excited by the radiation emanating from lamp 102 and radiates light inside the fiber. This light is radiated omni-

directionally and the part of it that is within the critical angle of fiber 105 is trapped and propagates through the fiber and can be used at fiber output 104. The angle of light that is trapped in the fiber is the critical angle of the material from which the optical fiber or optical wave guide is made. For a fiber (or optical wave guide) in air this angle is given by $\sin \alpha = 1/n$.

Typically for glass or other transparent materials $n = 1.5$ and $\alpha = 41.8^\circ$. This corresponds to a trapping efficiency of more than 10% of the light emitted by fluorescence inside the fiber. If we assume a 50% efficiency of the fluorescence process we find out that more than 5% of the light produced by the lamp is trapped and propagated down the fiber. For example, a 4" lamp with a linear electrical energy input of 300J/inch and 50% electrical to light conversion efficiency would couple 2.5% of its electrical energy into the fiber. This corresponds, for the 4" lamp case to a total light energy of 30J of light. This embodiment has the additional advantage of transferring the wavelength emitted by the lamp to a wavelength that may be more useful in some of the therapeutic or processing applications mentioned before. Thus, fluorescent material doped in the fiber can be chosen in accordance with an emission wavelength determined by the specific application of the device.

One alternative embodiment includes the use of a gel to couple the light to the skin. This alternative reduces heating of the outer layer of the skin (the epidermis and upper layers of the dermis). The gel is preferably a high viscosity water based gel and is applied to the skin before treatment, although other gels that are not necessarily water based may be used. A gel having a relatively high heat capacity and thermal conductivity, such as a water based gel, is preferable to enable cooling of the outer skin (the epidermis in particular). Transparency is also desirable because during treatment light passes through the transparent gel and reaches the skin.

Referring now to Figure 13, a gel 110 is applied to the skin 21 prior to the treatment. A flat layer of gel on top of the skin is used since irregularities in the upper layer of the gel through which the light passes may cause scattering of the light and reduce its penetration into the skin. In order to achieve this flatness a solid, transparent, flat piece 111 may be applied on top of the skin. The configuration is shown schematically in Figure 13. The transparent plate can be made out of glass or other transparent materials. Either the flashlamp housing or the light guides discussed above may be placed in direct contact with the transparent plate.

The configuration of Figure 13 has the advantage of reducing the scattering of light (represented by arrows 113) that enters into the skin due to irregularities in the surface of the skin. The skin has an index of refraction that is larger than that of the air. As a result, any photon that impinges on the air/skin interface is deflected if it does not hit the skin at an incidence angle of 0° . Since the surface of the skin is irregular the angular distribution of the skin increases. This is shown schematically in Figure 14.

The use of gel addresses this problem since the gel can fill irregular voids that are created by the skin structure. The transparent plate that covers the gel and the gel itself will preferably have an index of refraction that is close to that of the skin. This is relatively easy since the index of refraction of the skin is of the order of 1.4 in the visible and the near infrared. Most glasses and transparent plastics have indices of refraction that are of the order of 1.5 which is close enough. The index of refraction of water is of the order of 1.34 in this range. Water based gels will have similar indices of refraction. The index can be increased by proper additives. The plate and gel thus act as a flat surface for the light to impinge upon. Because the gel and plate have an index of refraction close to that of the skin there is very little scattering at the gel-plate and gel-skin interfaces.

The use of a gel has been experimentally successful in the treatment of leg veins and other benign vascular lesions of the skin. The treatments were carried out with the flashlamp described above. However, in alternative embodiments a different incoherent source, or a coherent source, may be used.

During operation light is typically applied to the skin in a sequence of three pulses with short delays between the pulses. This mode of operation is used in order to take advantage of the faster cooling of the superficial, thin (less than 0.1mm thick) epidermis compared to the larger and deeper vessels typical of leg veins. The gel in contact with the skin cools the epidermis during the waiting period between the pulses. This cooling reduces significantly the damage to the epidermis.

In accordance with the invention, light is applied to the treated area in either a long pulse or in a sequence of pulses separated by a delay. The delay and/or pulse length is preferably controlled by the operator to provide enough heat to accomplish the desired treatment but not enough heat to damage the skin.

This concept was tested with large and deep vessels (of the order of 2mm in diameter and 2mm deep). A thin layer of commercial water based ultrasound gel (1 to 2mm thick, "Aqua clear" gel made by Parker USA) was applied on the skin. A 1mm thin glass window was used to generate a flat layer of the gel. The light from the device passed through the thin glass and the gel and into the skin. Care was taken to assure that no air bubbles exist in the gel. This configuration was tested with photon fluences of 30 to 50J/cm². Coagulation and clearance of the vessels was obtained without causing damage to the skin. This is contrary to similar trials in which gel was not used and in which fluences of 20J/cm² with the same pulse structure caused burns of the skin.

The epidermis has a thickness of approximately 0.1 mm and a cooling time of about 5 msec. Thus, to avoid burning delays greater than 5 msec are used.

In another alternative embodiment the spectrum of the light used for treatment is controlled by controlling the voltage and/or current applied to the flashlamp. As is well known in the art, the spectrum of light produced by a flashlamp is dependent on the voltage and current provided to the flashlamp. According to this embodiment the input voltage and current is selected to provide a desired treatment spectrum. The appropriate voltage and currents may be determined experimentally for each flashlamp used. For example, a flashlamp current of 200 amps produced the spectra shown in Figure 17. Similarly, the spectra of Figure 18 was produced using a flashlamp current of 380 amps. The spectra of Figure 17 shows a significant enhancement in the wavelength range of 800-1000nm. Such a spectra is particularly useful for treatment of large vessels.

The different currents and voltages used to control the output spectra may be obtained using a group or bank of capacitors that are capable of being connected in either series or parallel as part of the power source for the flashlamp. A series connection will provide a relatively high voltage and high current, thereby producing a spectra having energy in a shorter wavelength, such as 500-650 nm. Such a series connection will be more appropriate for generating shorter pulses (1 to 10 msec, e.g.) useful for treatment of smaller vessels.

A parallel connection provides a lower current and voltage, and thus produces an output spectra of a longer wavelength, such as 700-1000 nm. Such a spectra is more appropriate for treatment of larger vessels and is suitable for producing longer pulses (in the range of 10-50 msec, e.g.). The selection of series or parallel connections may be done using a relay or sets of relays.

In one alternative embodiment the pulse forming network of Figure 3 is replaced by a GTO driver circuit 121, such as that shown in Figure 19. The driver circuit of Figure 19 uses a switch capable of being turned both on and off to control the application of power to the flashlamp. While this alternative embodiment will be described with respect to a GTO being used as the switch, other switches capable of being turned both on and off, such as IGBTs, may also be used.

Referring now to Figure 19, driver circuit 121 includes a high voltage source 122, a capacitor bank C5, an inductor L5, a diode D5, a switch GTO1, a diode D6, a diode D7, a resistor R5, a capacitor C6, a GTO trigger generator TR1, a resistor R7, a capacitor C7 and a flashtube trigger generator TR2. These components are connected to flashlamp 14 and serve to provide the power pulses to flashlamp 14. The duration and timing of the pulses are provided in accordance with the description herein. Driver 121 operates in the manner described below.

High voltage source 122 is connected across capacitor bank C5, and charges capacitor bank C5 to a voltage suitable for application to flashlamp 14. Capacitor bank C5 may be comprised of one or more capacitors, and may be configured in the manner described above.

Prior to illumination of flashlamp 14 flashtube trigger generator TR2 breaks down flashlamp 14 and creates a relatively low impedance channel therein. After the flashlamp breaks down, capacitor C7 dumps current into flashlamp 14, further creating a low impedance channel in flashlamp 14. In this manner a pre-discharge is provided that prepares flashlamp 14 for the power pulse. Capacitor C7 provides a small amount of current, relative to capacitor bank C5. Alternatively, driver circuit 121 may operate in a simmer mode, wherein the pre-discharge is not necessary.

Thereafter, switch GTO1 is turned on via a pulse from GTO trigger generator TR1, completing the circuit between flashlamp 14 and capacitor bank C5. Thus, capacitor bank C5 discharges through flashlamp 14. An inductor L5 may be provided to control the rise time of the current through flashlamp 14. Inductor L5 may include an inherent resistive component, not shown.

After a length of time determined by the desired pulse width has passed, GTO trigger generator TR1 provides a pulse to switch GTO1, turning it off. A control circuit determines the timing of the trigger pulses and provides them in accordance with the desired pulse widths and delays.

A snubber circuit comprised of diode D6, resistor R5, and a capacitor C6 is provided for switch GTO1. Also, diodes D5 and D7 are provided to protect switch GTO1 from reverse voltages. Resistor R7 is provided in parallel with flashlamp 14 to measure the leakage current of switch GTO1, which can in turn be used to make sure that switch GTO1 is operating properly.

A possible addition to driver circuit 121 is to provide an SCR or other switch in parallel with capacitor bank C5. This allows the discharge or resetting of capacitor bank C5 without turning on switch GTO1. Other modifications may be made, such as providing the circuit with a serial trigger, rather than the parallel trigger shown. Another modification is to use the driver circuit with a laser rather than flashlamp 14.

Proper use of pulse widths and delays can aid in avoiding burning the epidermis. The epidermis has a cooling time of about 5 msec, while large vessels have a longer cooling time (a 1 mm vessel has a cooling time of about 300 msec). Thus, during a pulse of duration longer than 5 msec the epidermis can cool down but the vessel will not. For example, for treatment of a large vessel (such as one having a diameter of about 1mm) a pulse of 100 msec will allow the skin to cool, but the vessel will not cool.

The same effect may be achieved using trains of pulses. This is useful when it is not practical to provide a single long pulse to the flashlamp. The delays between pulses are selected to allow the skin to cool, but to be too short for the vessel to cool. Thus, larger vessels can be treated with longer delays because they have greater cooling times. Small vessels cool quickly and long delays are not effective. However, they also need less energy and can be treated effectively in a single pulse.

Typical delay times are in the range of 20 msec to 500 msec. More specifically, delays of between 100-500 msec are effective for vessels larger than 1 mm in diameter. Delays of between 20-100 msec are effective for vessels between 0.5 and 1 mm in diameter. Delays of between 10-50 msec are effective for vessels between 0.1 and 0.5 mm in diameter. A single pulse having a width in the range of 1 msec to 20 msec is effective for vessels less than 0.1 mm diameter.

5 Additionally, delays should be selected according to skin pigmentation. Darker skin absorbs more energy and needs more time to cool; thus longer delays are needed. Lighter skin absorbs less energy and can accommodate shorter delays.

It has been found that multiple pulses avoids "purpura" or the explosion of small vessels in or close to the skin. The use of pulses to avoid burning and provide cooling will be effective for light provided by lasers or other sources as well.

10 Another alternative embodiment includes the use of a microprocessor or personal computer to control the flashlamp. The microprocessor can be used to provide the timing functions and prompt the trigger signals described above. Additionally, in one embodiment the microprocessor includes a user interface, such as a screen and keyboard, buttons, mouse, or other input device. The microprocessors have information stored therein that aids in the selection of treatment parameters.

15 For example, if the condition being treated is a port wine stains skin type III, the physician inputs that condition into the microprocessor. The microprocessor responds with suggested treatment parameters, such as using a 570nm cut-off filter, a double pulse with a delay of 50 msec and a fluence of 55 J/cm². The physician can alter these suggested parameters, but need not refer back to operating guidelines for suggested parameters.

20 The microprocessor or personal computer can also be used to create and store patient information in a database. Thus, past treatment information such as condition being treated, treatment parameters, number of treatments, etc. is stored and may be recalled when the patient is again treated. This aids in providing the proper treatment to the patient. Additionally, the database may include photographs of the patient's condition before and after each treatment. Again, this aids in record keeping and determining what treatments are most successful for given conditions.

25 In addition to the treatments described above the devices and methods described herein may be used to treat other conditions. For example, psoriasis and warts have been successfully treated. Similarly, skin rejuvenation (treating wrinkles) should be effective. The inventor further contemplates using this invention to treat hemorrhoids, throat lesions, and gynecological problems associated with vascular malformations.

30 Thus, it should be apparent that there has been provided in accordance with the present invention a flashlamp and coupler that fully satisfy the objectives and advantages set forth above. Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

Claims

- 35 1. A therapeutic treatment device for treating a treatment region comprising an incoherent, pulsed, light source operable to provide a light output for treatment, a power supply connected to the light source, a housing including a reflector and having an opening, wherein the light source is disposed within the housing and the reflector reflects light from the light source to the opening, and a flexible light guide is disposed between the opening and the treatment region, wherein the light guide receives the incoherent light from the light source and transmits the light to the treatment region and the light source, reflector and light guide cooperate to provide between 6 and 100 J/cm² to the skin, characterized in that:
the light guide transmits light having a predetermined angular divergence, wherein the divergence is selected in response to a desired treatment depth.
- 40 2. The treatment device of claim 1 further characterized in that:
a first interference filter is disposed between the light source and the light guide; and
a second absorbing filter is disposed between the first filter and the treatment region.
- 45 3. The treatment device of claim 3 further characterized in that:
the light guide is made from a material including an absorbing dye and is the second absorbing filter.
- 50 4. The treatment device of claim 1 further characterized in that the reflector includes a reflecting portion that is a portion of a circle.
- 55 5. The treatment device of claim 4 further characterized in that the reflecting portion is relatively close to the light source.
6. The treatment device of claim 5 further characterized in that a cooling gel is disposed over the treatment area.

EP 0 724 894 A2

7. A method for therapeutically treating a treatment region comprising the steps of producing incoherent, pulsed, light in a housing, reflecting the light to an opening in the housing, transmitting the light from the opening to the treatment area through a light guide to provide between 6 and 100 J/cm² to the skin, characterized in that:
the light guide transmits light such that the light has a predetermined angular divergence and the divergence is selected in response to a desired treatment depth.
8. The treatment method of claim 7 further characterized in that:
the light is filtered by a first interference filter, between the light source and the light guide; and
the light is filtered by a second absorbing filter between the first filter and the treatment region.
9. The treatment method of claim 8 further characterized in that:
the light is filtered by the second absorbing filter as the light passes through the light guide.
10. The method device of claim 7 further characterized in that the step of reflecting includes the step of reflecting the light by a reflector that a portion of a reflecting surface is a portion of a circle.
11. The treatment method of claim 10 further characterized in that the reflecting portion is relatively close to the light source.
12. The treatment method of claim 7 further including the step of applying a cooling gel to the treatment area.

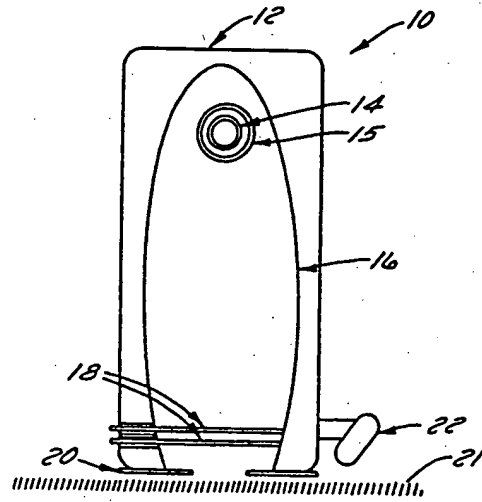


FIG. 1

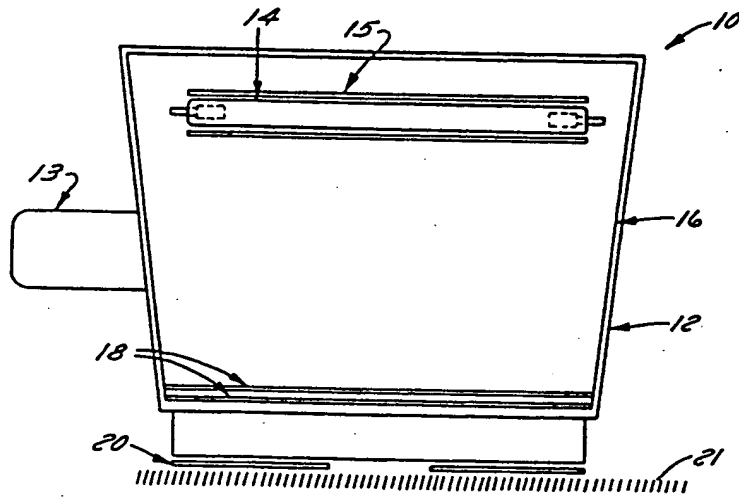


FIG. 2

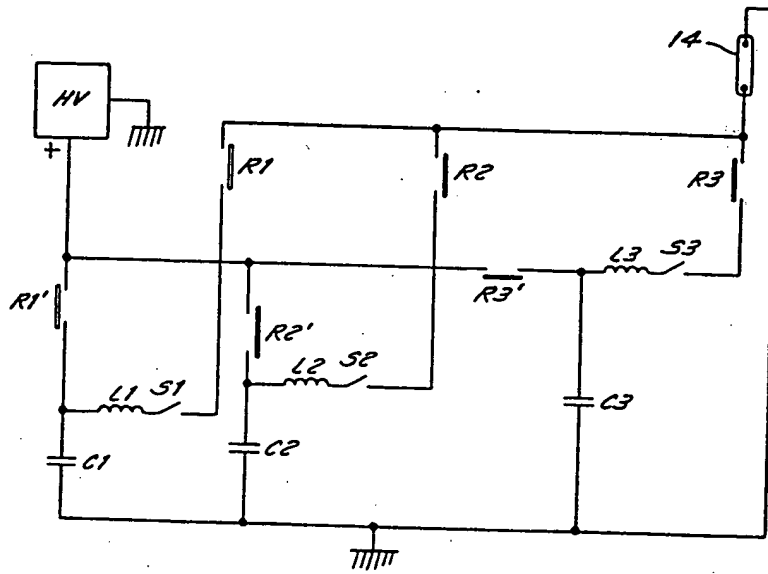


FIG. 3

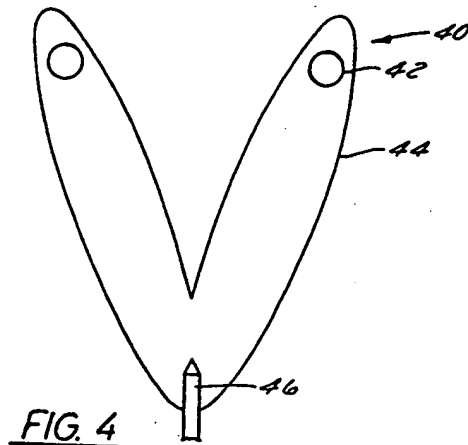


FIG. 4

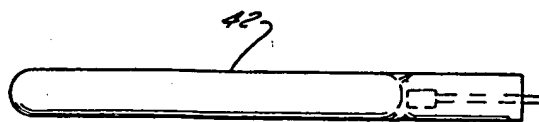


FIG. 5

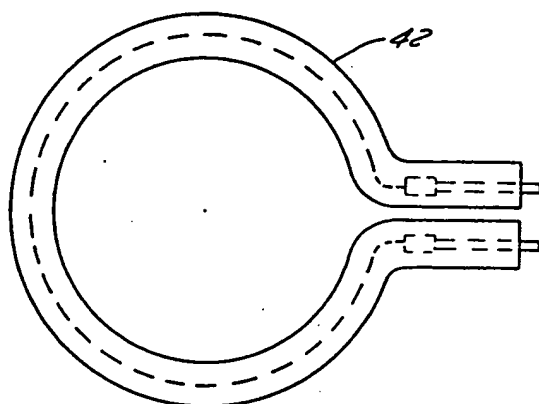


FIG. 6

10

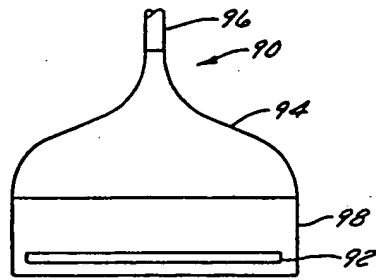


FIG. 9

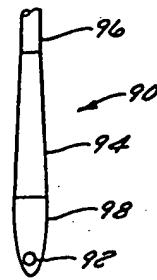


FIG. 10

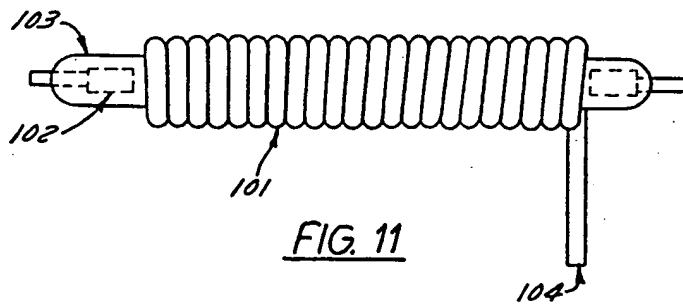


FIG. 11

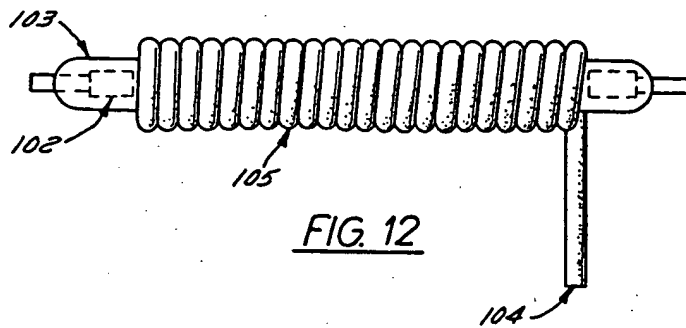


FIG. 12

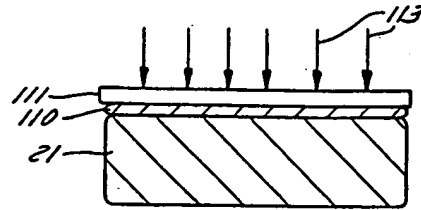


FIG. 13

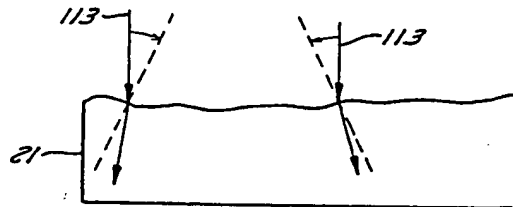


FIG. 14

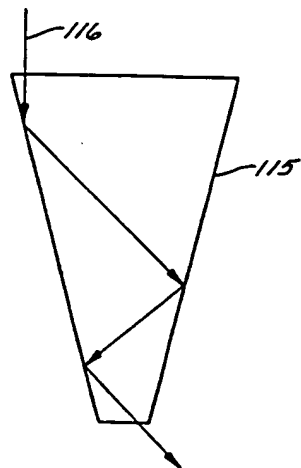


FIG. 15

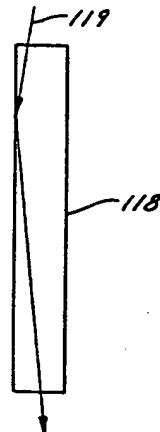
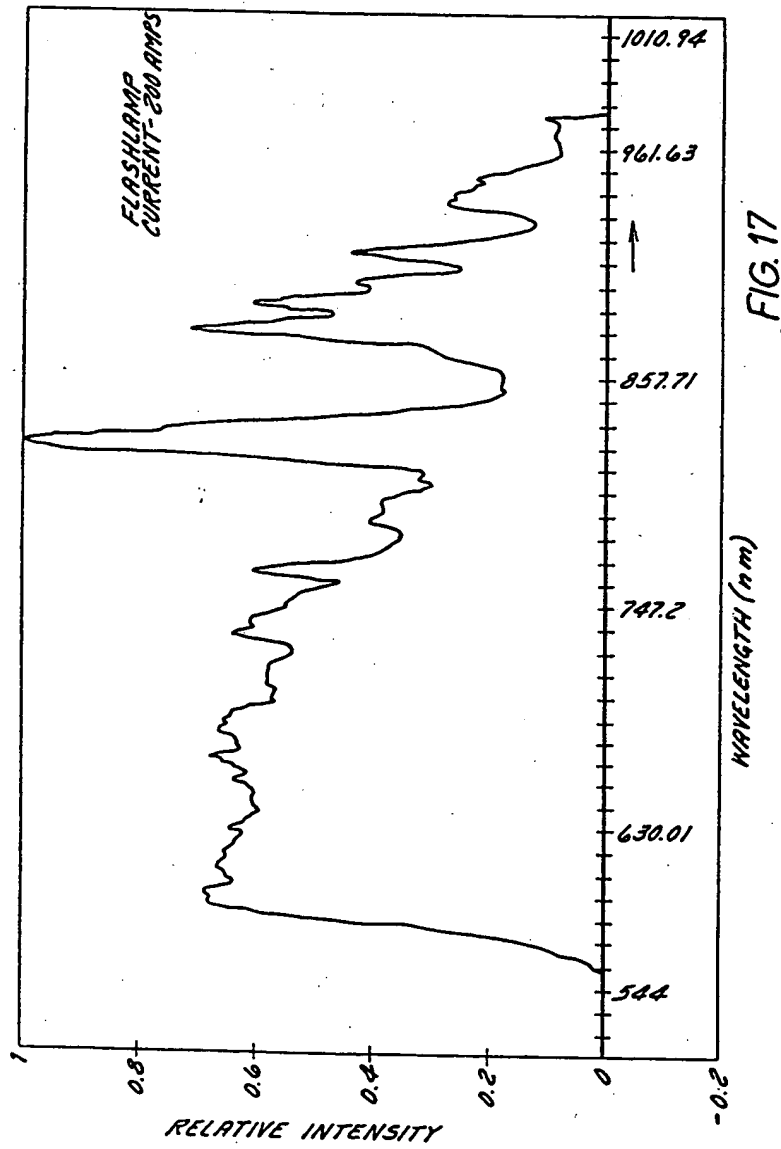
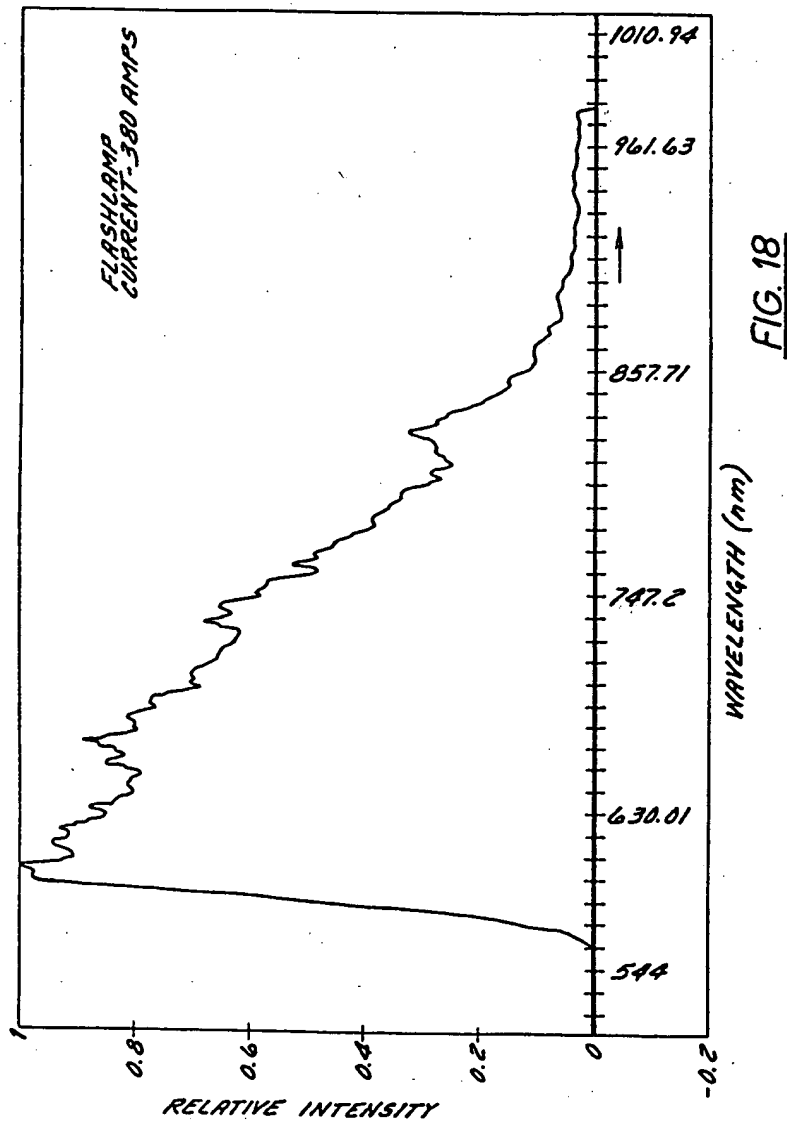


FIG. 16





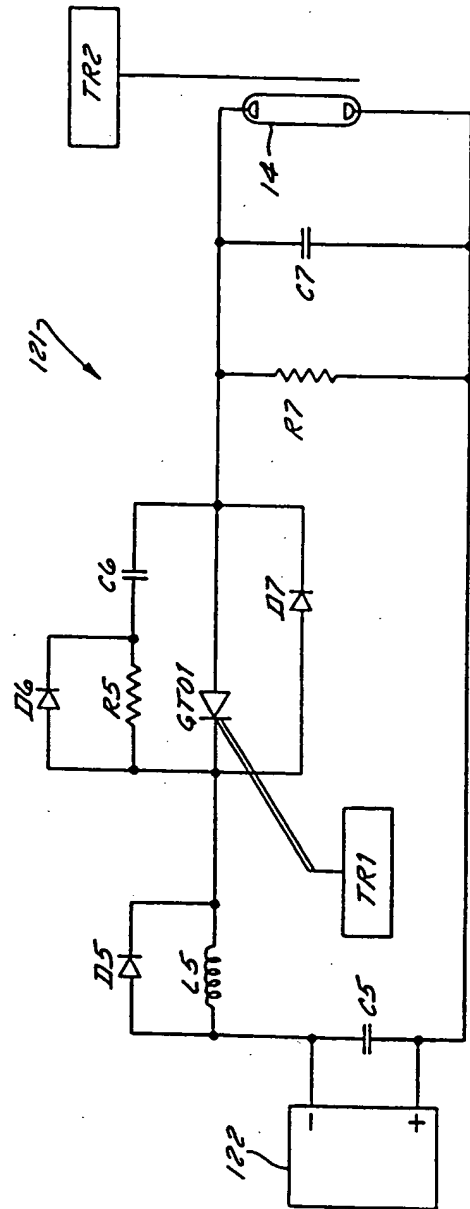


FIG. 19